



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

January 15, 2008

**MEMORANDUM**

**Subject:** Efficacy Review for DisCide ULTRA Disinfecting Towelettes, EPA Reg. No. 10492-4; DP Barcode: D357773.

**From:** Ibrahim Laniyan, Microbiologist  
Product Science Branch  
Antimicrobials Division (7510P)

**Thru:** Tajah Blackburn, Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Marshall Swindell / Martha Terry  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**Applicant:** Palmero Health Care  
120 Goodwin Place  
Stratford, CT 06615

**Formulation from the Label:**

<u>Active Ingredient</u>	<u>% by wt.</u>
n-alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chloride.....	0.12 %
n-alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	
dimethyl ethyl benzyl ammonium chloride.....	0.12 %
Isopropyl alcohol.....	63.25 %
<u>Inert Ingredients.....</u>	<u>36.51 %</u>
<u>Total.....</u>	<u>100.00 %</u>

## I. BACKGROUND

The product, DisCide ULTRA Disinfecting Towelettes (EPA Reg. No. 10492-4), is an Agency approved disinfectant towelette (bactericide, tuberculocide, virucide, fungicide) for use on hard, non-porous surfaces in institutional, commercial, food service, animal care, and hospital or medical environments. The applicant requested to amend the product registration to add claims for effectiveness as a disinfectant against *Candida albicans* and *Proteus mirabilis*. The label claims a reduced contact time against Avian Influenza (H3N2) virus, Influenza A virus, and Human Coronavirus. Studies, conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121, were submitted with the product DisCide ULTRA Disinfecting Spray, EPA Reg. No. 10492-5 in the data package D357772.

This data package contained a letter from the applicant representative to EPA (dated September 29, 2008), and the proposed label (Date September 29, 2008).

## II. USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous, non-food contact surfaces such as appliance exteriors, baskets, bassinets, bathroom fixtures, bed rails, cabinets, carts, cell phones, chairs, child-restraint seats, computer keypads, computer screens, counter tops, diaper pails, drawer pulls, door knobs and handles, exercise and weight-lifting equipment, flooring, incubators, lighting fixtures, office equipment, physical therapy equipment, shopping carts, shower stalls, sinks, stools, tables, telephones, toilet exteriors, toilet seats, trash cans, vanities, and walls. The label indicates that the product may be used on hard, non-porous surfaces including: Formica, glass, and stainless steel. Directions on the proposed label provided the following information regarding use of the product as a disinfectant against viruses: Thoroughly wet the surface with the towelette product. Allow to remain wet for 1 minute.

## III. CONCLUSIONS

1. The reviewed efficacy data (MRID 475543-01 through 475543-05) **support** the use of the **liquid, non-towelette product**, **DisCide ULTRA Disinfecting Spray**, as a disinfectant against the following microorganisms on hard, non-porous surfaces at room temperature in the presence of a 5% organic soil load for the following contact times:

<i>Candida albicans</i>	1 minute	MRID 475543-01
Avian Influenza A (H3N2) virus	30 seconds	MRID 475543-02
Influenza A virus	30 seconds	MRID 475543-03
Human Coronavirus	30 seconds	MRID 475543-04
<i>Proteus mirabilis</i>	1 minute	MRID 475543-05

## IV. RECOMMENDATIONS

1. The proposed label claims that the product, DisCide ULTRA Disinfecting Towelettes, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 1 minute:

*Candida albicans*  
*Proteus mirabilis*

Data provided by the applicant **support** these claims. Acceptable efficacy results against *S. aureus* (ATCC 6538) (MRID 440006-07), *S. enterica* (ATCC 10708) (MRID 440006-07), *P. aeruginosa* (ATCC 15442) (MRID 440006-07), *Mycobacterium bovis* (BCG) (MRID 465672-01) and *T. mentagrophytes* (ATCC 9533) (MRID 440006-08), allow for bridging of *Candida albicans* and *Proteus mirabilis* to the proposed label.

2. The proposed label claims that the product, DisCide ULTRA Disinfecting Towelettes, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 30 seconds:

Avian Influenza A (H3N2) virus  
Influenza A virus  
Human Coronavirus

Data provided by the applicant **do not support** these claims. To support bridging of these viral claims, the most difficult to inactivate non-enveloped virus, Adenovirus Type 2 virus (the most resistant virus listed on the label) or anyone of these three viruses, must be tested for 30 seconds contact time using DisCide ULTRA Disinfecting Towelettes. **Thirty seconds contact time claims must be removed from the label.**